

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 020916**

**CHEMISTRY REVIEW(S)**

JUN 11 1998

**DIVISION OF SPECIAL PATHOGEN  
AND IMMUNOLOGIC DRUG PRODUCTS**  
Review of Chemistry, Manufacturing, and Controls

**NDA #: 20-916**

**CHEMISTRY REVIEW #: 1**

**DATE REVIEWED: June 4, 1998**

<b>SUBMISSION</b>	<b>DOCUMENT DATE</b>	<b>CDER DATE</b>	<b>ASSIGNED DATE</b>
Original	September 30, 1997	September 30, 1997	October 9, 1997
New Correspondence	December 5, 1997	December 11, 1997	December 17, 1997

**NAME & ADDRESS OF SPONSOR:** Astra Merck, Inc.  
725 Chesterbrook Blvd.  
Wayne, PA 19087

**DRUG PRODUCT NAME**

Proprietary: PRILOSEC® Delayed Release Capsules  
Nonproprietary: Omeprazole  
Code Name/#:

**PHARMACOLOGICAL CATEGORY:** H<sup>+</sup>/K<sup>+</sup> ATPase enzyme inhibitor

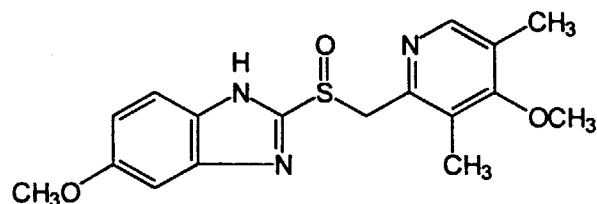
**INDICATION:** Omeprazole in combination with amoxicillin and clarithromycin for reduction of risk of duodenal ulcer recurrence.

**DOSAGE FORM/STRENGTH:** Capsules, 20 mg

**ROUTE OF ADMINISTRATION:** Oral

**CHEMICAL NAME/STRUCTURAL FORMULA:**

5-Methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridyl)methyl]sulfinyl]-1H-benzimidazole



**MOLECULAR FORMULA:** C<sub>17</sub>H<sub>19</sub>N<sub>3</sub>O<sub>3</sub>S

**MOLECULAR WEIGHT:** 345.42

**CAS:** 73590-58-6

**SUPPORTING DOCUMENTS:**

IND IND IND NDA 19-810 NDA 20-754

**RELATED DOCUMENTS:**

**REMARKS/COMMENTS:**

This NDA proposes a treatment regimen consisting of PRILOSEC® (omeprazole, 20 mg bid), amoxicillin (1 g bid) and clarithromycin (500 mg bid) for reduction of risk of duodenal ulcer recurrence. No changes in the chemistry or manufacture of PRILOSEC® are being proposed. The application does not propose a combination product or combined packaging, nor are there any changes proposed in the chemistry section of the labeling. An Environmental Assessment has been submitted. This was referred to the EA group for consultation, and a Finding of No Significant Impact was issued on Jan 14, 1998.

**CONCLUSIONS & RECOMMENDATIONS:**

From a CMC view point, this application may be approved.

APPEARS THIS WAY  
ON ORIGINAL

/S/ 6-4-98  
Gene W. Holbert, Ph.D., Review Chemist

APPEARS THIS WAY  
ON ORIGINAL

Concurrence:  
HFD-590/NSchmuff  
cc:  
Orig. NDA 20-916  
HFD-590/Div. File  
HFD-590/SHundley  
File: N20-916.000

/S/ 6/11/98  
v  
HFD-590/RHopkins  
HFD-590/NSchmuff  
HFD-590/LUtrup

HFD-590/RAnderson  
HFD-590/GHolbert  
HFD590/HMahayni